was pervasive enough to create an abusive work environment.

E. *Constructive Knowledge of Terry's Unfitness Under Florida Negligent Retention Law.*

Finally, Faragher and Ewanchew contend that the district court erred in finding that, for purposes of their negligent supervision claims, the City did not have actual or constructive notice of Terry's conduct. Our review of the record leads us to agree with the City that the district court's finding that the City had no notice of Terry's conduct is not clearly erroneous.

VI. CONCLUSION

We reverse the district court's judgment for Faragher on her Title VII sexual harassment claim against the City. In all other respects, we affirm the district court's judgment.

AFFIRMED IN PART; REVERSED IN PART.

In re Norman K. ALTON, Mary A. Peters, Yitzhak Tabinsky, and David L. Snitman.

No. 94-1495.

United States Court of Appeals, Federal Circuit.

Feb. 5, 1996.

Patent applicant appealed from ruling of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences, ruling that specification in patent application did not provide adequate written descriptive support for amino acids sequence of human gamma interferon described in claim. The Court of Appeals, Schall, Circuit Judge, held that: (1) patent examiner erred in viewing declaration of applicant's expert as opinion evidence addressing question of law rather than question of fact, and (2) patent examiner erred by dismissing declaration of applicant's expert, addressing issue of whether patent specification adequately described subject matter recited in claim, without adequately explaining how declaration failed to overcome prima facie case supporting rejection.

Vacated and remanded.

1. Patents ⇐314(5)

Issue of whether patent specification adequately describes subject matter of claim is question of fact. 35 U.S.C.A. § 112.

2. Patents ⇐324.55(2)

Court of Appeals reviews questions of fact arising from Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences rejections of patent application under clearly erroneous standard and reviews questions of law de novo.

3. Patents ⇐98

Adequate written description requirement, which is distinct from enablement and best mode requirements, serves to ensure that inventor had possession, as of filing date of patent application relied on, of specific subject matter later claimed by him or her; how specification accomplishes this is not material. 35 U.S.C.A. § 112.

4. Patents ⇐98

In order to be considered enabling, patent must give persons of ordinary skill in relevant art enough information to practice invention disclosed in specification without undue experimentation. 35 U.S.C.A. § 112.

5. Patents ⇐98

Best mode requirement mandates that inventor disclose best mode known to him or her at time patent application is filed. 35 U.S.C.A. § 112.

6. Patents ⇐98

In order to meet adequate written description requirement, patent applicant does not have to utilize any particular form of disclosure to describe subject matter

claimed, but description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed. 35 U.S.C.A. § 112.

7. Patents ⇐98

To satisfy adequate written description requirement, patent applicant must convey with reasonable clarity to those skilled in the art that, as of filing date sought, he or she was in possession of invention. 35 U.S.C.A. § 112.

8. Patents ⇐98

Precisely how close original description in patent application must come to comply with adequate written description requirement must be determined on case by case basis. 35 U.S.C.A. § 112.

9. Patents ⇐104

Patent examiner erred in viewing declaration of applicant's expert as opinion evidence addressing question of law rather than question of fact, in determining whether application provided adequate written descriptive support for amino acid sequence of human gamma interferon described in claim; expert's declaration offered factual evidence in attempt to explain why one of ordinary skill in the art would have understood specification to describe modification involving deletion of first three amino acids in sequence independently of modification at 81st position. 35 U.S.C.A. § 112.

10. Patents ⇐314(5)

Question of whether patent specification provides adequate written description of subject matter of claims is issue of fact. 35 U.S.C.A. § 112.

11. Patents ⇐99

In determining whether patent application for amino acid sequence of human gamma interferon satisfied written description requirement, patent examiner erred by dismissing declaration of applicant's expert, addressing issue of whether example in specification adequately described analog set forth in claim, without adequately explaining how declaration failed to overcome prima facie case supporting rejection; examiner did not address expert's argument that one of ordinary skill in the art would have understood specification to describe two separate modifications to amino acid sequence independently. 35 U.S.C.A. § 112.

12. Patents ⇐104

Patent examiner, or Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences, if Board is first body to raise particular ground for rejection, bears initial burden of presenting prima facie case of unpatentability. 35 U.S.C.A. § 112.

13. Patents ⇐104

Insofar as written description requirement is concerned, burden of presenting prima facie case of unpatentability is discharged by presenting evidence or reasons why persons skilled in the art would not recognize in disclosure description of invention as defined by claims. 35 U.S.C.A. § 112.

14. Patents ⇐104

If applicant claims embodiments of invention that are completely outside scope of specification, then examiner or Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences need only establish this fact to make out prima facie case of invalidity; if, on the other hand, specification contains description of claimed invention, albeit in identical words, then examiner or Board, in order to meet burden of proof, must provide reasons why one of ordinary skill in the art would not consider description sufficient. 35 U.S.C.A. § 112.

15. Patents ⇐104

Once patent examiner or Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences carries burden of making out prima facie case of unpatentability, burden of coming forward with evidence or argument shifts to applicant. 35 U.S.C.A. § 112.

16. Patents ⇐104

To overcome prima facie case of unpatentability, patent applicant must show that invention as claimed is adequately described to one skilled in the art. 35 U.S.C.A. § 112.

17. Patents ⇐99

If person of ordinary skill in the art would have understood inventor to have been in possession of claimed invention at time of filing, even if every nuance of claims is not explicitly described in specification, then adequate written description requirement is met. 35 U.S.C.A. § 112.

Appealed from U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

Michael F. Borun, Marshall, O'Toole, Gerstein, Murray & Borun, Chicago, Illinois, argued for appellants. With him on the brief was Li–Hsien Rin–Laures. Also on the brief was Steven M. Odre, Thousand Oaks, California. Of counsel were Robert R. Cook and Ron K. Levy, Thousand Oaks, California.

Scott A. Chambers, Associate Solicitor, Office of the Solicitor, Arlington, Virginia, argued for appellee. With him on the brief were Nancy J. Linck, Solicitor, Albin F. Drost, Deputy Solicitor and Richard Torczon, Associate Solicitor.

Before MICHEL, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and SCHALL, Circuit Judge.

SCHALL, Circuit Judge.

Appellants Norman K. Alton, et al. ("Alton"), appeal the ruling of the United States Patent and Trademark Office Board of Patent Appeals and Interferences ("Board") in Appeal No. 94–3098. In its decision, the Board held that the specification of application serial number 06/483,451 ("the '451 application") did not provide adequate written descriptive support for the amino acid sequence of human gamma interferon ("IFN-γ") described in claim 70. We vacate the decision and remand the case to the Board for further proceedings.

1. We understand the parties to be in agreement on the facts regarding the technology in this case.

2. Amino acids, of which there are twenty, are small organic molecules. Benjamin Lewin, *Genes V* 11 (1994). Amino acids combine in linear chains to form proteins. *Id.* at 14. A protein is sometimes referred to as a polypeptide.

3. The 146–amino acid sequence of the IFN-γ analog recited in claim 70 is attached to this opinion.

BACKGROUND

I.

IFN-γ is a protein secreted by cells in the human immune system to stimulate immunological activity.[1] Patrick W. Gray et al., *Expression of Human Immune Interferon cDNA in E. Coli and Monkey Cells*, 295 Nature 503 (1982). IFN-γ is believed useful because it activates macrophages, which are a class of cells in the immune system. Bruce Alberts et al., *Molecular Biology of the Cell* 1048, 1049 (2d ed. 1989). IFN-γ is composed of a sequence of 146 amino acids.[2] The complete sequence is divided into four subunits. IFN-γ polypeptides containing alterations in the naturally-occurring amino acid sequence are called "analogs."

Claim 70 of the '451 application, set forth below, recites an analog of IFN-γ:

> [Met^{-1}, des-Cys^{1}, des-tyr^{2}, des-cys^{3}] IFN-γ polypeptide produced by a DNA sequence coding therefor in a transformant organism, said product having substantially the characteristics of human immune interferon.

(brackets in original). The bracketed words at the beginning of the claim indicate how the claimed IFN-γ differs from the natural version of IFN-γ.[3] "Met," "cys," and "tyr" are abbreviations for three of the twenty amino acids; they stand for methionine, cysteine, and tyrosine, respectively. A positive superscripted number following the abbreviation of an amino acid indicates the position of that amino acid in the 146 amino acid chain that comprises IFN-γ. For example, "tyr^{2}" means that tyrosine is the second amino acid in the 146 amino acid chain. The designation "des" preceding the name of the amino acid indicates that that particular amino acid has been deleted and no amino acid has been substituted in its place. Therefore, "[des-cys^{1}, des-tyr^{2}, des-cys^{3}]" means that the cysteine at position one of the amino acid chain

has been removed, as has the tyrosine at position two and the cysteine at position three. A negative superscripted number indicates that an amino acid has been added onto the beginning (the N-terminus) of the IFN-γ sequence. Thus, "met^{-1}" means that a methionine has been placed at the beginning of the IFN-γ amino acid chain.

In sum, the analog of IFN-γ recited in claim 70 has two characteristics that distinguish it from the natural version of IFN-γ. First, as "[des-cys^1, des-tyr^2, des-cys^3]" indicates, the first three amino acids—cysteine, tyrosine, and cysteine—of the natural 146 amino acid sequence have been deleted from the claimed IFN-γ analog. These three amino acids are located on the fourth subunit ("IF–4") of the complete sequence. Second, methionine has been placed at the beginning of the amino acid sequence of the claimed analog.

The '451 application's specification contains twelve examples of IFN-γ analogs. Of these, Example 5 is closest to the analog that is the subject of claim 70. Like claim 70, it discloses deletion of the first three amino acids and placement of methionine at the beginning of the amino acid sequence of IFN-γ ("[met^{-1}, des-cys^1, des-tyr^2, des-cys^3]"). Unlike claim 70, however, Example 5 additionally discloses substitution of asparagine—the eighty-first amino acid in the IFN-γ chain—with lysine, another amino acid ("lys^{81}"). The eighty-first amino acid is located on the second subunit ("IF–2") of the IFN-γ sequence.

II.

The '451 application was filed April 15, 1983. It is a continuation-in-part of a parent application filed on May 6, 1982, and later abandoned. The examiner issued a final rejection of the claims of the '451 application as anticipated under 35 U.S.C. § 102(e) and rendered obvious over the prior art under 35 U.S.C. § 103.

Alton appealed the examiner's final rejection to the Board. On February 28, 1991, the Board reversed the examiner's section 102 and 103 rejections but rejected the claims on the new ground that the specification failed to describe adequately the subject matter of the claims, as required by 35 U.S.C. § 112, ¶ 1. The Board stated: "The closest analog to that claimed herein is described [in Example 5]. This particular analog, though similar to that claimed herein, does not constitute a description of the claimed analog."

Electing further prosecution pursuant to 37 C.F.R. 1.196(b),[4] Alton submitted to the examiner, in response to the Board's section 112, ¶ 1 rejection, a declaration by Dr. Randolph Wall (the "Wall declaration"). In due course, the examiner issued a final rejection on the same grounds as had the Board. Alton then requested reconsideration; the examiner denied the request and maintained his rejection ("final rejection").

Alton appealed the final rejection of claim 70 to the Board. The examiner filed his Answer and the Board sustained the section 112, ¶ 1 rejection on June 21, 1994. In its decision, the Board held that "the specific polypeptide of claim 70 was not *described* in the original specification of application Serial No. 06/483,451." The Board adopted the examiner's dismissal of the Wall declaration, in which the examiner reasoned that the declaration was opinion evidence rather than factual evidence. The examiner stated, "Little weight is given an opinion affidavit on the ultimate legal question at issue." This appeal followed.

DISCUSSION

I.

[1, 2] The issue of whether a patent specification adequately describes the subject

4. 37 C.F.R. § 1.196(b) (1994) states:
When the Board of Patent Appeals and Interferences makes a new rejection of an appealed claim, the appellant may ... submit ... a showing of facts ... and have the matter reconsidered by the examiner in which event the application will be remanded to the examiner. The statement shall be binding upon the examiner unless an amendment or showing of facts not previously of record be made which, in the opinion of the examiner, overcomes the new ground for rejection stated in the decision. Should the examiner again reject the application the applicant may again appeal to the Board of Patent Appeals and Interferences.

matter claimed is a question of fact. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed.Cir.1991). We review questions of fact arising from Board rejections under a clearly erroneous standard. *In re Caveney*, 761 F.2d 671, 674, 226 USPQ 1, 3 (Fed.Cir.1985). We review questions of law *de novo*. *Electronic Design & Sales, Inc. v. Electronic Data Systems Corp.*, 954 F.2d 713, 715, 21 USPQ2d 1388, 1390 (Fed.Cir.1992).

II.

Alton contends that the Board committed clear error in holding that the '451 specification did not describe the subject matter of claim 70. Alton additionally argues that the Board erred in failing to give substantial weight to the Wall declaration.

The adequate written description requirement of 35 U.S.C. § 112, ¶ 1, provides that

> [t]he specification shall contain a *written description of the invention*, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(emphasis added).

[3–8] The adequate written description requirement, which is distinct from the enablement and best mode requirements,[5] serves "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material." *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). In order to meet the adequate written description requirement, the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, but "the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed.Cir. 1989) (citation omitted). Put another way, "the applicant must ... convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*." *Vas-Cath*, 935 F.2d at 1563–64, 19 USPQ2d at 1117. Finally, we have stated that "[p]recisely how close the original description must come to comply with the description requirement of section 112 must be determined on a case-by-case basis." *Eiselstein v. Frank*, 52 F.3d 1035, 1039, 34 USPQ2d 1467, 1470 (Fed.Cir.1995) (quoting *Vas-Cath*, 935 F.2d at 1561, 19 USPQ2d at 1116).

As noted above, following the Board's decision of February 28, 1991, Alton elected further prosecution pursuant to 37 C.F.R. § 1.196(b). In that context, Alton submitted the Wall declaration in response to the Board's section 112, ¶ 1 rejection. In paragraph 9J of his declaration, Dr. Wall addressed the issue of whether Example 5 in the specification described what was claimed in claim 70: [6]

> J. The specific modifications of subunit IF–4 for deleting both cysteines and the intermediate tyrosine at amino acid positions 1, 2, and 3 are set out at page 50, lines 11 and 12, which describe modification of the IF–4 subunit (which contains a methionyl residue-specifying codon at position –1) to contain the codons,
>
> 5'-ATG CAG–3'
>
> 3'-TAC GTC–5'
>
> in the amino acid specifying region. ATG is a codon specifying methionine; CAG is a

5. In order to be considered enabling, a patent must give persons of ordinary skill in the relevant art enough information to practice the invention disclosed in the specification without undue experimentation. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed.Cir.1984). The best mode requirement mandates that the inventor disclose the best mode known to him or her at the time the patent application is filed. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535, 3 USPQ2d 1737, 1745 (Fed.Cir.), *cert. denied*, 484 U.S. 954, 108 S.Ct. 346, 98 L.Ed.2d 372 (1987).

6. The parties do not dispute that Dr. Wall has the requisite skill in the art.

codon specifying glutamine. Expression of a complete, four subunit, DNA sequence with this modification in subunit IF–4 operatively provides a polypeptide of claims 70.... It is my opinion that a skilled worker in molecular biology and the cloning and expression of genes, would, in 1983, have understood the proposed modification [des-cys[1], des-tyr[2], des-cys[3]] to have been described independently of any suggestion to alter the arginine [sic: asparagine[7]] residue at position 81 of mature human immune interferon. While the specific analog including both the changes in the mature human immune interferon was described as being made and tested, that compound was noted to be an "example" of polypeptide analogs wherein cysteines were deleted for the purpose of facilitating isolation of analogs by destroying the possibility of intermolecular disulfide bridge[8] formation. Modifying the residue at position 81 would have no effect on this property because neither arginine [sic: asparagine] nor lysine can participate in disulfide bridge formation. Moreover, changing to [sic] residue at position 81 would involve a modification in subunit IF–2, requiring an entirely separate series of manipulations of the complete DNA sequence to generate this different class of analog.

Among other things, the Wall declaration states that one of ordinary skill in the art in 1983 would have known, first, that a problem involved with isolating analogs was the capacity of the amino acid sequence to form bonds with itself through disulfide bridges, and second, that deletion of cysteines would eliminate this phenomenon. According to Dr. Wall, one of ordinary skill in the art would have understood the discussion in the specification of Example 5 to be offered as an illustration of the deletion of cysteines. Therefore, according to Dr. Wall, one of ordinary skill in the art, knowing that deleting the first three amino acids of the complete sequence would affect disulfide bridge formation but that the existence of lysine at position 81 would not, would have understood the specification to describe the two modifications independently. Also according to Dr. Wall, a second reason one of ordinary skill in the art would have understood the specification to describe the two modifications independently is that the first three amino acids are located on subunit IF–4, whereas the eighty-first amino acid is located on subunit IF–2.

In his final rejection, which was adopted by the Board, the examiner stated that the specification did not convey that Alton had possession of the subject matter of claim 70 as of April 15, 1983—the filing date of the '451 application. In support of the rejection, referring to Example 5, the examiner asserted that the only example in the specification that described deletion of the first three amino acids and placement of methionine at the beginning of the amino acid sequence of IFN-γ additionally described substitution of asparagine—the eighty-first amino acid in the IFN-γ chain—with lysine, another amino acid. Turning to the Wall declaration, the examiner stated:

> In order to support patentability of the claims Dr. Wall points to the same text of the specification as previously identified by the Board of Patent Appeals and Interferences as being insufficient. Importantly, Dr. Wall arrives at a conclusion which is opposite that determined by the Board.... In view of the previous discussion of the Board of Patent Appeals and Interferences and the evidence of record, this argument is not found to be persuasive....
>
> The weight given to the 132 Declaration by Dr. Wall, in particular paragraph ... 9J, depends on whether it presents allegations, opinions or facts. In this case the Declaration does not point to inherent support

7. We understand the parties to be in agreement that recitation in the Wall declaration of the amino acid "arginine," instead of "asparagine," was a typographical error.

8. Cysteines contain a sulfur atom. The sulfur atom of a cysteine in an amino acid chain can bond to the sulfur atom in a second cysteine at another location in the same amino acid sequence. Benjamin Lewin, *Genes V* 14 (1994). The resulting cysteine-cysteine bond, known as a disulfide bridge, causes the amino acid chain to bend back on itself. *Id.*

> or evidence to support the conclusory statement in paragraph 9J. Little weight is given an opinion affidavit on the ultimate legal question at issue.

In short, the examiner rejected Dr. Wall's opinion that "a skilled worker in molecular biology and the cloning and expression of genes, would, in 1983, have understood the proposed modification to have been described independently of any suggestion to alter the arginine [sic] residue at position 81 of mature human immune interferon." The examiner maintained this position in his Answer. In his Answer, the examiner stated that

> the Wall Declaration does not suggest that the written description in the specification supports an interferon-gamma which *must* have the claimed structure. Indeed, the number of possible interferon-gamma analogs encompassed by the written description of the invention is substantial and the specification does not lead to any compound which must have the claimed structure.

As already seen, the Board adopted as its own the examiner's response to Alton's arguments.

We express no opinion on the factual question of whether the specification adequately describes the subject matter of claim 70.[9] We do, however, hold that the examiner's final rejection and Answer contained two errors: (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's prima facie case of inadequate description.

III.

A. *The Examiner Erred by Mistaking a Question of Fact for a Question of Law*

[9] As seen above, in his final rejection, the examiner stated that the weight given to Dr. Wall's declaration

> depends on whether it presents allegations, opinions or facts. In this case the Declaration does not point to inherent support or evidence to support the conclusory statement in paragraph 9J. Little weight is given an opinion affidavit on the ultimate legal question at issue.

In his Answer, the examiner continued that

> [i]t is apparently the "*opinion*" (emphasis added) of Dr. Wall that, as of the filing date of this application, one skilled in the art would have interpreted ... the specification as specific guidance for a class of interferon analogs lacking the cys-tyr-cys residues at the amino terminus.... Little weight is given an opinion affidavit on the ultimate legal question at issue regarding written description for the invention now claimed.

[10] It is well settled that the question of whether a specification provides an adequate written description of the subject matter of the claims is an issue of fact. Therefore, the examiner was in error when he stated that the Wall declaration, which attempted to shed light on whether the '451 specification adequately described the subject matter of claim 70, addressed a legal issue.

Additionally, the examiner interpreted the Wall declaration as offering opinion evidence, rather than factual evidence, on the adequate written description issue. The Wall declaration's assertion that "[m]odifying the residue at position 81 would have no effect on [disulfide bridge formation] because neither [asparagine] nor lysine can participate in disulfide bridge formation" is a factual statement, however. So too is the statement that changing the amino acid at position 81 would involve a modification in subunit IF-2, "requiring an entirely separate series of manipulations of the complete [amino acid] sequence to generate this different class of analog." We do not read the declaration as asserting an opinion on the patentability of the claimed IFN-γ analog. Rather, the declaration is offering factual evidence in an attempt to explain *why* one of ordinary skill in the art would have understood the specification to describe the modification involving

9. *See Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed.Cir.1993) ("If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, ... then a description also requires that degree of specificity.").

the deletion of the first three amino acids independently of the modification at position 81. Dr. Wall's use of the words "it is my opinion" to preface what someone of ordinary skill in the art would have known does not transform the factual statements contained in the declaration into opinion testimony.[10] Consequently, the examiner's dismissal of the declaration on the grounds that "[l]ittle weight is given an opinion affidavit on the ultimate legal question at issue" was error.

B. *The Examiner Erred by Failing to Articulate Adequate Support for the Rejection*

[11–16] The examiner also erred by dismissing the Wall declaration without an adequate explanation of how the declaration failed to overcome the prima facie case initially established by the Board—the rejection on the ground that the application failed to describe the subject matter of claim 70. The examiner (or the Board, if the Board is the first body to raise a particular ground for rejection) "bears the initial burden ... of presenting a prima facie case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed.Cir.1992). Insofar as the written description requirement is concerned, that burden is discharged by "presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. Thus, the burden placed on the examiner varies, depending upon what the applicant claims. If the applicant claims embodiments of the invention that are completely outside the scope of the specification, then the examiner or Board need only establish this fact to make out a prima facie case. *Id.* at 263–64, 191 USPQ at 97. If, on the other hand, the specification contains a description of the claimed invention, albeit not *in ipsis verbis* (in the identical words), then the examiner or Board, in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient. *Id.* at 264, 191 USPQ at 98. Once the examiner or Board carries the burden of making out a prima facie case of unpatentability, "the burden of coming forward with evidence or argument shifts to the applicant." *Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444. To overcome a prima facie case, an applicant must show that the invention as claimed is adequately described to one skilled in the art. "After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of the evidence with due consideration to persuasiveness of argument." *Id.* at 1445, 24 USPQ2d at 1444.

[17] After claim 70 was first rejected on section 112, ¶ 1 grounds, Alton submitted evidence to rebut the rejection in the form of the Wall declaration.[11] The Wall declaration contained statements of fact directly addressing the issue of whether the specification adequately described the subject matter recited in claim 70. The purpose of the adequate written description requirement is to ensure that the inventor had possession of the claimed subject matter at the time the application was filed. If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met. For example, in *Ralston Purina Co. v. Far-Mar Co., Inc.*, 772 F.2d 1570, 1576, 227 USPQ 177, 180 (Fed.Cir.1985), the trial court admitted expert testimony about known industry standards regarding temperature and pressure in "the art of extrusion of both farinaceous and proteinaceous vegetable materials." The effect of the testimony was to expand the breadth of the actual written description since it was apparent that the

10. In any event, we are aware of no reason why opinion evidence relating to a fact issue should not be considered by an examiner. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294, 227 USPQ 657, 665 (Fed.Cir. 1985), *cert. denied*, 475 U.S. 1017, 106 S.Ct. 1201, 89 L.Ed.2d 315 (1986).

11. We are satisfied that the Board met its prima facie case of establishing lack of adequate written description in its February 28, 1991 decision by discussing Example 5 of the specification, in which both modifications appeared together.

inventor possessed such knowledge of industry standards of temperature and pressure at the time the original application was filed. Similarly, the Wall declaration in essence attempts to expand the breadth of the specification by arguing that a person of ordinary skill in the art would have understood the two modifications in Example 5 of the specification to be described independently of each other and thus a description of both modifications would include a description of either separately.

The thrust of the examiner's response to the Wall declaration, in both the final rejection and the Answer, is that the specification must describe the precise analog claimed. This explains why the examiner stated that the Wall declaration was inadequate because it did not "suggest that the written description in the specification supports an interferon-gamma analog which *must* have the claimed structure." This argument, however, does not address the point that paragraph 9J of the Wall declaration attempts to make: that one of ordinary skill in the art would have understood the specification to describe the two modifications ([met^{-1}, des-cys^{1}, des-tyr^{2}, des-cys^{3}] and lys^{81}) independently and that the description of both modifications together would be relevant as an example of only one of those modifications ([met^{-1}, des-cys^{1}, des-tyr^{2}, des-cys^{3}]). Thus, according to the Wall declaration, the specification would be understood to describe the relevant modification ([met^{-1}, des-cys^{1}, des-tyr^{2}, des-cys^{3}]) without the irrelevant one (lys^{81}). Therefore, according to the Wall declaration, one of ordinary skill in the art would understood Alton to be in possession, in 1983, of the claimed subject matter, which contained the [met^{-1}, des-cys^{1}, des-tyr^{2}, des-cys^{3}] modification but not the modification at position 81.

The Wall declaration addresses why the claimed subject matter, although not identical to the analog described in the specification, was in Alton's possession. The statement in the examiner's answer that the number of possible analogs encompassed by the specification is substantial does not rebut the thrust of the Wall declaration because the Wall declaration explains why one of ordinary skill in the art would have realized that Alton had possession of one particular analog. In sum, in his final rejection and again in his Answer, the examiner dismissed the Wall declaration and provided only conclusory statements as to why the declaration did not show that a person skilled in the art would realize that Alton had possession of the claimed subject matter in 1983.

CONCLUSION

First, by concluding that the Wall declaration addressed an issue of law instead of an issue of fact, and second, by failing to articulate adequate reasons to rebut the Wall declaration, the examiner and Board failed to consider the totality of the record for the purpose of issuing a final rejection and thus erred as a matter of law. We are not in a position, however, to determine whether the specification contained an adequate written description of the claimed IFN-γ sequence. That determination requires, in the first instance, further proceedings in which the Wall declaration is addressed in a manner that is consistent with this opinion. The case is remanded to the Board for such further proceedings. *See In re Beaver,* 893 F.2d 329, 13 USPQ2d 1409 (Fed.Cir.1989) (vacating Board's decision for failing to review all the appealed claims in accordance with the relevant regulations).

COSTS

Each side to pay its own costs.

VACATED AND REMANDED.

ATTACHMENT A

```
1                                                  10
Cys-Tyr-Cys-Gln-Asp-Pro-Tyr-Val-Lys-Glu-Ala-Glu-Asn-Leu-
TGT TAC TGC CAG CAG CAA TAT GTA AAA GAA GCA GAA AAC CTT

                        20
Lys-Lys-Tyr-Phe-Asn-Ala-Gly-His-Ser-Asp-Val-Ala-Asp-Asn-
AAG AAA TAT TTT AAT GCA GGT CAT TCA GAT GTA GCG GAT AAT

    30                                                  40
Gly-Thr-Leu-Phe-Leu-Gly-Ile-Leu-Lys-Asn-Trp-Lys-Glu-Glu-
GGA ACT CTT TTC TTA GGC ATT TTG AAG AAT TGG AAA GAG GAG

                                    50
Ser-Asp-Arg-Lys-Ile-Met-Gln-Ser-Gln-Ile-Val-Ser-Phe-Tyr-
AGT GAC AGA AAA ATA ATG CAG AGC CAA ATT GTC TCC TTT TAC

            60                                                  70
Phe-Lys-Leu-Phe-Lys-Asn-Phe-Lys-Asp-Asp-Gln-Ser-Ile-Gln-
TTC AAA CTT TTT AAA AAC TTT AAA GAT GAC CAG AGC ATC CAA

                                            80
Lys-Ser-Val-Glu-Thr-Ile-Lys-Glu-Asp-Met-Asn-Val-Lys-Phe-
AAG AGT GTG GAG ACC ATC AAG GAA GAC ATG AAT GTC AAG TTT

                        90
Phe-Asn-Ser-Asn-Lys-Lys-Lys-Arg-Asp-Asp-Phe-Glu-Lys-Leu-
TTC AAT AGC AAC AAA AAG AAA CGA GAT GAC TTC GAA AAG CTG

    100                                                 110
Thr-Asn-Tyr-Ser-Val-Thr-Asp-Leu-Asn-Val-Gln-Arg-Lys-Ala-
ACT AAT TAT TCG GTA ACT GAC TTG AAT GTC CAA CGC AAA GCA

                                    120
Ile-His-Glu-Leu-Ile-Gln-Val-Met-Ala-Glu-Leu-Ser-Pro-Ala-
ATA CAT GAA CTC CTC ATC CAA ATG GCT GAA CTG TCG CAA GCA

            130                                                 140
Ala-Lys-Thr-Gly-Lys-Arg-Lys-Arg-Ser-Gln-Met-Leu-Phe-Gln-
GCT AAA ACA GGG AAG CGA AAA AGG AGT CAG ATG CTG TTT CAA
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